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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/525,364

09/22/2005

Arun Kumar Dhar

026086-041.-28US

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24239 7590 05/14/2009
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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

05/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/525,364 | Applicant(s) DHAR ET AL. | |
| | Examiner S. Devi, Ph.D. | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-10,12,17-26 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 1, 5-10, 12 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-26 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>030309 & 011909</u> . | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 03/02/09 in response to the non-final Office Action mailed 10/02/08.

Status of Claims

- 2) Claims 1, 5, 12 and 17-26 have been amended via the amendment filed 03/02/09.
Claims 2-4, 11, 13-16 and 27-31 have been canceled via the amendment filed 03/02/09.
New claims 32-38 have been added via the amendment filed 03/02/09.
Claims 1, 5-10, 12, 17-26 and 32-38 are pending.
Claims 17-26 and 32-34 are under examination.

Information Disclosure Statements

- 3) Acknowledgment is made of Applicants' Information Disclosure Statements filed 03/03/09 and 01/19/09. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) to Specification

- 6) 37 CFR 1.75(d)(1) provides, in part, that 'the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'

Claims 17 and 21, as amended, include the new limitations: 'capable of *reducing* ... binding of a disease-causing agent in one or more cells of the animal, wherein the recombinant viral protein or peptide consists of a sequence *for a* WSSV or TSV protein selected from the group

consisting of VP24, VP28, VP26, VP19, *LGBP* and TSV capsid protein', which lack clear antecedent basis in the as-filed specification. Claim 18 includes the new limitation 'untruncated' recombinant viral peptide or protein, which lacks clear antecedent basis in the as-filed specification.

Rejection(s) Moot

7) The rejection of claim 31 made in paragraph 7(d) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

8) The rejection of claim 31 made in paragraph 7(e) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

9) The rejection of claims 28-31 made in paragraph 9 of the Office Action mailed 10/02/08 under 35 U.S.C. § 102(e)(2) as being anticipated by Frenken *et al.* (US 6,517,829 - Applicants' IDS) as evidenced by van Hulten *et al.* (*J. General Virol.* 81: 2525-2529, 2000), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

10) The rejection of claims 18 and 24 made in paragraph 7(a) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

11) The rejection of claims 19, 20 and 26 made in paragraph 7(c) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

12) The rejection of claim 24 made in paragraph 7(f) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim. A new rejection is set forth below to address the claim as amended.

13) The rejection of claims 19 and 20 made in paragraph 7(g) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.

14) The rejection of claims 17-26 made in paragraph 9 of the Office Action mailed 10/02/08 under 35 U.S.C. § 102(e)(2) as being anticipated by Frenken *et al.* (US 6,517,829 - Applicants'

IDS) as evidenced by van Hulten *et al.* (*J. General Virol.* 81: 2525-2529, 2000), is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) Maintained

15) The rejection of claim 18 made in paragraph 7(b) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein. Applicant has not specifically addressed the rejection.

16) The rejection of claims 24 and 25 made in paragraph 7(c) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein. Applicant has not specifically addressed the rejection.

17) The rejection of claim 23 made in paragraph 7(d) of the Office Action mailed 10/02/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein. Applicant has not specifically addressed the rejection. It is suggested that Applicants replace the above-identified limitation with the limitation --encapsulated purified protein, or encapsulated semi-purified protein--.

18) The rejection of claims 17-26 made in paragraph 9 of the Office Action mailed 10/02/08 under 35 U.S.C. § 102(e)(2) as being anticipated by Frenken *et al.* (US 6,517,829 - Applicants' IDS) as evidenced by van Hulten *et al.* (*J. General Virol.* 81: 2525-2529, 2000), is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

19) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20) Claims 17, 18, 21 and the dependent claims 18-26 and 32-34 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 17 and 21, as amended, include the new limitations: 'capable of *reducing* ... binding of a disease-causing agent in one or more cells of the animal' and '*a sequence for a WSSV or*

.... TSV protein selected from the group consisting of VP24, VP28, VP26, VP19, *LGBP* and TSV' [Emphasis added]. Note that the limitation 'a disease-causing agent' encompasses disease-causing agents other than WSSV or TSV, including bacterial, fungal and parasitic disease-causing agents, HIV disease-causing agent, cancer disease-causing agent etc. Applicants state that support for the amendment can be found at paragraphs [012], [015], [042] and [052] of the specification. However, these parts of the specification do not provide descriptive support for the limitations identified above. While paragraph [0015] of the specification is supportive of the delivery of the protein, inhibiting or 'retarding' binding of *the agent that causes the disease* in one or more cells of the animal, it does not provide support for one or more recombinant VP24, VP28, VP26, VP19, LGBP or TSV capsid protein capable of 'reducing' or even inhibiting binding of any generic disease-causing agent, including non-WSSV or non-TSV disease-causing agent. The recited recombinant viral protein or peptide consisting of a sequence "for" a WSSV or TSV protein selected from the group consisting of VP28, VP24, VP26, VP19, LGBP or TSV capsid protein is not supported in the as-filed specification. Claim 18 includes the new limitation: 'untruncated' recombinant viral peptide or protein. Applicants state that support for the amendment can be found at paragraph [049] of the specification. However, this paragraph does not include a recitation of the term 'untruncated recombinant viral peptide or protein'. Therefore, the instant claim(s) are considered as comprising new matter. *In re Rasmussen*, 650 F.2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

21) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

22) Claims 17-26 and 32-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 18 lacks proper antecedent basis in the limitation ‘peptide’. Claim 18 depends from claim 17, which already includes the limitation. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the peptide--.

(b) Analogous rejection and criticism apply to the dependent claims 19 and 21-25 with regard to the limitation ‘peptide’.

(c) Claims 17 and 21 are inconsistent and confusing in the limitation: ‘a sequence **for**’ WSSV or TSV and ‘a sequence **of**’ WSSV or TSV [Emphasis added] respectively, because it is unclear how the former differs from the latter in terms of scope.

(d) Claim 17, as amended, includes the new limitations: ‘capable of reducing ... binding of a disease-causing agent in one or more cells of the animal’ and ‘a sequence for a WSSV or TSV protein selected from the group consisting of LGBP’. Note that the limitation ‘a disease-causing agent’ encompasses disease-causing agents other than WSSV or TSV, including bacterial, fungal and parasitic disease-causing agents, HIV disease-causing agent, cancer disease-causing agent etc. Does it mean that the recited recombinant viral protein or peptide consisting of a sequence ‘for’ WSSV or TSV comprised in the claimed feed reduces or inhibits the binding of a non-WSSV or non-TSV disease-causing agent such as a cancer disease-causing agent? Does the limitation ‘a sequence for’ WSSV or TSV mean that it is not of WSSV or TSV origin?

(e) Analogous rejection and criticism apply to the dependent claim 21, as amended, with regard to the new limitation: ‘capable of reducing ... binding of a disease-causing agent in one or more cells of the animal’.

(f) Claims 18 and 24 are vague and indefinite in the limitation: ‘similar binding affinities’. The term ‘similar’ is a relative term which renders the claim indefinite. The limitation ‘similar binding affinities’ is not specifically defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of binding, and therefore, one of ordinary skill in the art would not be reasonably appraised of the scope of the claim.

(g) Claim 17 is incorrect and is inconsistent with claim 21 in the limitation: Taura Syndrome ‘Virus’.

(h) Claims 17 and 21, as amended, are indefinite and/or incorrect in the limitation: ‘the recombinant *viral* protein or peptide consists of a sequence selected from the group consisting of LGBP’ [Emphasis added]. Does it mean that ‘LGBP’ is a viral protein, WSSV protein, or TSV protein? Paragraphs [042] and [0036] of the specification appear to indicate that LGBP is a shrimp protein.

(i) Claim 34 is incorrect and indefinite because it lacks proper antecedent basis in the limitation: ‘algae is’. Claim 34 depends from claim 20, which already includes the plural limitation ‘algae’. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the algae are--.

(j) Claims 18-26 and 32-34, which depend directly or indirectly from claim 17, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

23) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24) Claims 17-26, 32 and 33 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kyle *et al.* (US 2004/0047881 A1 - Applicants’ IDS).

Instant claims get the effective filing date of the instant application, i.e., 09/22/05, due to the new matter identified above.

The transitional limitation ‘comprising’ similar to the limitation, such as, ‘having’ ‘including’, ‘containing’, or ‘characterized by’, represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (‘comprising’ leaves ‘the claim open for the inclusion of unspecified ingredients even in major amounts’). On the other hand, the limitation ‘consisting of’ represents closed claim language and excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App.

1948).

Kyle *et al.* disclosed a feed or a feed additive for an animal such as a crustacean shrimp comprising one or more recombinant proteins, peptides, or immunogenic epitopes thereof (i.e., truncated proteins) including VP28, VP24, VP26, or VP19, which inhibit the growth or replication of viral pathogens such as White Spot Syndrome Virus. The protein or the peptide is expressed via transformed host cells *E. coli* bacteria, algae such as *Chlorella* strains, yeast such as *Saccharomyces*, or other fungi. See abstract; Figure 2; paragraphs [0022], [0024], [0025], [0044], [0047] to [0052] and [0059]; Examples 9, 3 and 4; and claims 1-7, 9, 12, 13, 15, 23, 24, 28-33, 35-39, 52-60, 71, 72, 76-82, 84, 86-88, 92, 93 and 97. That the prior art one or more recombinant proteins or peptides such VP28, VP24, VP26, or VP19 consist intrinsically of an amino acid sequence is inherent from the teachings of Kyle *et al.* The recombinantly produced prior art protein or peptide is at least semi-purified since it does not contain other antigens of White Spot Syndrome Virus.

Claims 17-26, 32 and 33 are anticipated by Kyle *et al.*

Rejection(s) under 35 U.S.C. § 103

25) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth In *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

26) Claim 34 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kyle *et al.* (US 2004/0047881 A1 - Applicants' IDS) as applied to claim 20 above, and further in view of

Nakamura *et al.* (JP 2000354490 A, abstract).

The teachings of Kyle *et al.* (1998) are described above which do not expressly teach that the *Chlorella* strain they used is *Chlorella vulgaris*.

However, it was well known in the art at the time of the invention that the *Chlorella* strain routinely used as a host cell to express a protein or a peptide is *Chlorella vulgaris*. For example, Nakamura *et al.* taught the routine use of *Chlorella vulgaris* as a host cell for recombinant expression of a protein or a peptide. See abstract.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Nakamura's *Chlorella vulgaris* strain in place of Kyle's generically recited *Chlorella* strain to produce the instant invention with a reasonable expectation of success. Substitution of one art-known *Chlorella* strain with another, alternative, art-known strain of *Chlorella* strain such as Nakamura's *Chlorella vulgaris* strain for the same purpose of expressing a protein or peptide was well within the realm of routine experimentation, would have been obvious to one of ordinary skill in the art, and would have brought about similar predictable results.

Claim 34 is *prima facie* obvious over the prior art of record.

Relevant Art

27) The prior art made of record and not currently relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Klimpel (WO 2005/023992) disclosed a feed for a crustacean comprising a VP28 peptide that is capable of inhibiting infection due to White Spot Syndrome Virus in said crustacean. See claims 21, 22, 13 and 1.

Remarks

28) Claims 17-26 and 32-34 stand rejected.

29) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

30) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

31) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

32) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

May, 2009